

CLAIMS

1. Topical hormonal composition with systemic effect for the correction of progesterone deficiency in premenopausal women and for hormone replacement in menopausal women, characterized in that it includes :

- as active principle, a progestogen derived from 19-nor progesterone,
- a vehicle permitting the systemic passage of the said active principle chosen from the group comprising a solubilizing agent, an absorption promoter, a film-forming agent, a gelling agent or their mixtures,

10 (combined with or mixed with suitable excipients for the production of a gelled and/or film-forming pharmaceutical form.

2. Topical hormonal composition with systemic effect according to claim 1, characterized in that the progestogen derived from 19-nor progesterone is nomegestrol and/or one of its esters or ethers.

3. Topical hormonal composition with systemic effect according to claim 1 or claim 2, characterized in that the progestogen derived from 19-nor progesterone is nomegestrol acetate.

20 4. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 3~~, characterized in that the quantity of nomegestrol or of one of its esters or ethers varies from 0.05 to 1% by weight of the total composition.

5. Topical hormonal composition with systemic effect according to claim 4, characterized in that the quantity of nomegestrol or of one of its esters or ethers is 0.4 % by weight of the total composition.

30 6. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 5~~, characterized in that the solubilizing agent is chosen from the group comprising water, alcohols, propyleneglycol, a C₈/C₁₀ polyoxyethylene glycosyl glyceride or their mixtures.

7. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 6~~, characterized in that the solubilizing agent is a ternary mixture of 95° ethanol / water /

propyleneglycol, in which the percentage of 95° ethanol varies from 30 to 50 %, that of water from 30 to 60 % and that of propyleneglycol from 2 to 20 %.

8. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 6~~, characterized in that the solubilizing agent is a quaternary mixture 95° ethanol / water / ~~Labrasol®~~ / propyleneglycol, in which the percentage of 95° ethanol varies from 30 to 50 %, that of water from 30 to 60 %, that of ~~Labrasol®~~ from 3 to 7 % and that of propyleneglycol from 2 to 20 %.

9. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 8~~, characterized in that the absorption promoter is chosen from the group consisting of isopropylideneglycerol, α-tocopheryl polyethyleneglycol 1000 succinate and monoethyl ether of diethylene glycol.

10. Topical hormonal composition with systemic effect according to claim 9, characterized in that the absorption promoter is isopropylideneglycerol.

11. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 10~~, characterized in that the gelling agent is chosen from the group consisting of cellulose derivatives and acrylic derivatives.

12. Topical hormonal composition with systemic effect according to claim 11, characterized in that the cellulose derivative is hydroxypropylmethylcellulose.

13. Topical hormonal composition with systemic effect according to claim 11, characterized in that the acrylic derivative is a carbomer.

14. Topical hormonal composition with systemic effect according to ^{claim 1} ~~any one of the claims 1 to 13~~, characterized in that the film-forming agent is chosen from the group consisting of cellulose derivatives, methacrylic derivatives and polyvinylpyrrolidone derivatives.

15. Topical hormonal composition with systemic effect according to claim 14, characterized in that the cellulose derivative is hydroxypropylmethylcellulose acetate succinate.

16. Topical hormonal composition with systemic effect according to claim 14, characterized in that the methacrylic derivative is an aqueous dispersion of an anionic copolymer of methacrylic acid and ethyl acrylate.

claims!

a₅ 17. Topical hormonal composition according to ^{claim 1} ~~any one of the claims 1 to 16~~, characterized in that it is in the form of a gel or a film-forming gel and in that it contains, in an aqueous-alcoholic mixture, 8 % of propyleneglycol and 3 % of isopropylidene glycerol.

add
a2

$\begin{pmatrix} H^{(0)} & H^{(1)} \\ \vdots & \vdots \end{pmatrix} = \begin{pmatrix} H_0 & H_1 \\ \vdots & \vdots \end{pmatrix}$